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EXAMINER	
QUAN, ELIZABETH S	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/934,865	NIERMANN, VOLKER	
	Examiner	Art Unit	
	Elizabeth Quan	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☒ Claim(s) *6 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 August 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because in section [0036], reference characters 120 and 40 are disclosed to be in fig. 2 but they are not seen in fig. 2. Furthermore, reference character 120 is not in any of the figures. Additionally, the drawings should more clearly reflect the spiraling of the capillary channel. The luer lock in fig. 6 should be more clearly drawn to show hollow areas since it is unclear what makes it a male-luer lock. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the capillary channel following a tortuous path at the end of path before venting, such that the vent must be shown or the feature(s) canceled from the claim(s). Additionally, it must be shown when the path in not tortuous. The following elements must also be shown: capillary channel with means for restricting fluid drawn therein since the current drawings show the means for drawing on the exterior of the housing, fluid stop supported by the channel intermediate the housing interior and access port, fluid valve, fibrous material plug, and removably attached male and female luer locks. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

1. The disclosure is objected to because of the following informalities: Referring to section [0026], first part **28** should be first part **26**.

Appropriate correction is required.

Claim Objections

2. Claim 6 is objected to because of the following informalities: "the" should be inserted before "end of path before venting". Appropriate correction is required.

3. Claim 19 is objected to because of the following informalities: "explosion" should be "expulsion". Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 6, 7, 20-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 6 is rendered indefinite by the recitation of "its not a tortuous path along the entire perimeter". It is unclear what the "its" is referring to.

7. Claim 7 is rendered indefinite since it is unclear whether the path is spiral from the drawings, making interpretation of "spiral" difficult.

8. Claims 20-23 are rendered indefinite since (210) is disclosed as being a male luer lock connection in the specification when it appears more of a female luer lock connection since it has

an opening through which the tip fits. Zhang et al. show this similar structure in fig. 32 and calls it a female-luer lock.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,001,307 to Naka et al. (EXAMPLE 5; fig. 7) as evidenced by U.S. Patent No. 5,958,344 to Levine et al.

Naka et al. disclose a fluid transfer device (EXAMPLE 5; fig. 7). A housing defines an interior and includes an access port (4) and elongate capillary channel (2a-c) in fluid communication with the access port and housing interior for drawing fluid through the access port at one end of a collection/dispensing tip (5c) and into the capillary channel under capillary action (EXAMPLE 5; fig. 7). The housing includes a bulb-shaped member defining the housing interior and capillary channel extending from the bulb-shaped member to the access port (fig. 7). The dimensions of the drawing channels and the like in this fluid transfer device are disclosed as being the same as that in the device of the prescribed embodiment having a bypass channel, which would be the device of EXAMPLE 3 as shown in fig. 3 (col. 16, lines 63-67). The capillary channel (2a) is usually 1-3 mm in width, and the capillary channel (2b), which is at one

end of the capillary channel (2a), is usually 0.1-0.5 mm in width (col. 13, lines 43-51). At another end of capillary channel (2a) is formed an opening (4), which is usually 1-3 mm in minimum width (col. 14, lines 3-10). The channel (2a-2c) is considered a capillary channel since the channels have capillary dimension as evidenced by Levine et al., which discloses that channels of capillary dimensions--dimensions that favor capillary flow of a liquid--are no wider than about 1.5 mm (Levine et al.: col. 2, lines 45-50). The housing includes an interiorly deformable contoured dimple (1), which is deformable so as to compress the interior of the housing (EXAMPLE 5; fig. 7). The dimple also defines the interior of the housing (EXAMPLE 5; fig. 7). After several compressions of the dimple, one would expect a noticeable concavity in the region where the dimple is, such that the dimple may be considered a contoured dimple. The invention focuses on compressing the housing to generate a suction pressure to suck fluid into the capillary channel. Since the channels are of capillary dimensions, the capillary channel is capable of drawing fluid through the access port and into the capillary channel under capillary action. Analogous to the operation of a pipette, compressing the housing generates a suction force to draw fluid into the capillary channel and compressing the housing now with fluid once again exerts an expelling force on the capillary channel to expel the fluid from the access port.

11. Claims 1-3, 5, 6, 8-11, 15, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,001,307 to Naka et al. (EXAMPLE 2; fig. 2) as evidenced by U.S. Patent No. 5,958,344 to Levine et al.

Naka et al. disclose a fluid transfer device (EXAMPLE 2; fig. 2). A housing defines an interior and includes an access port (4) and elongate capillary channel (2a,2b) in fluid communication with the access port and housing interior for drawing fluid through the access

port at one end of a collection/dispensing tip (5c) and into the capillary channel under capillary action (EXAMPLE 2; fig. 2). The housing includes a bulb-shaped member defining the housing interior and capillary channel extending from the bulb-shaped member to the access port (fig. 2). The housing includes a first housing member or base member and second housing member or covering attachable to the first housing member by adhesive to define the housing interior (fig. 2; col. 11, line 67-col. 12, line 3; col. 10, lines 7-9). The first housing member includes a sidewall, which borders the capillary channel and extends from the lowest level at which the groove forming the channel dips (figs. 1 and 2). The sidewall mates with the second housing member (figs. 1 and 2).

The second housing member includes an interiorly deformable contoured dimple (1), which is deformable so as to compress the interior of the housing (EXAMPLE 2; fig. 2). The dimple also defines the interior of the housing (EXAMPLE 2; fig. 2). The dimple is located within the perimeter of the housing (fig. 2). After several compressions of the dimple, one would expect a noticeable concavity in the region where the dimple is, such that the dimple may be considered a contoured dimple. The invention focuses on compressing the housing to generate a suction pressure to suck fluid into the capillary channel. Since the channels are of capillary dimensions, the capillary channel is capable of drawing fluid through the access port and into the capillary channel under capillary action. Analogous to the operation of a pipette, compressing the housing generates a suction force to draw fluid into the capillary channel and compressing the housing now with fluid once again exerts an expelling force on the capillary channel to expel the fluid from the access port.

The dimensions of the drawing channels and the like in this fluid transfer device are disclosed as being the same as that in the device of the prescribed embodiment of a device for analyzing a sample, which would be the device of EXAMPLE 1 as shown in fig. 1 (col. 12, lines 26-29). The capillary channel (2) is usually 1-3 mm in width (col. 10, lines 57-63). Since the opening at one end of the capillary channel appears to be the same width as that of the capillary channel, one would expect that the opening would also be usually 1-3 mm in width (fig. 2). The channel (2) is considered a capillary channel since the channels have capillary dimension as evidenced by Levine et al., which discloses that channels of capillary dimensions--dimensions that favor capillary flow of a liquid--are no wider than about 1.5 mm (Levine et al.: col. 2, lines 45-50). The capillary channel is formed neared the perimeter of the first housing member (fig. 2). The capillary channel follows a tortuous path near the housing perimeter, as shown by the bends in the capillary channel some of which are indicated by reference character (2a) (fig. 2). However, the path is not tortuous along the entire perimeter, as shown by the straight-line path along the perimeter having analytical section (3) (fig. 2). The access port is located adjacent the housing perimeter in communication with one end of the capillary channel (fig. 2). The other end of the capillary channel is in fluid communication with the interior of the housing (fig. 2). The capillary channel includes means for restricting fluid drawn therethrough by controlling channel configuration (col. 4, line 7-col. 5, line 24).

12. Claims 1, 3, 5, 6, 8-10, 12, 14, 15, 17, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,001,307 to Naka et al. (EXAMPLE 9; fig. 13) as evidenced by U.S. Patent No. 5,958,344 to Levine et al.

Naka et al. disclose a fluid transfer device (EXAMPLE 9; fig. 13). A housing defines an interior and includes an access port (4) and elongate capillary channel (2a,2b) in fluid communication with the access port and housing interior for drawing fluid through the access port at one end of a collection/dispensing tip and into the capillary channel under capillary action (EXAMPLE 9; fig. 13). The housing includes a first housing member or base member and second housing member or covering attachable to the first housing member by adhesive to define the housing interior (EXAMPLES 7 and 9; figs. 9 and 13; col. 22, lines 47-50; col. 20, lines 34-37). The first housing member includes a sidewall, which borders the capillary channel and extends from the lowest level at which the groove forming the channel dips (figs. 9 and 13). The sidewall mates with the second housing member (figs. 9 and 13). The housing includes a view window (10) in visual communication with the capillary channel (figs 9 and 13; col. 22, lines 47-50; col. 19, lines 10-20, 49, and 50).

The second housing member includes an interiorly deformable contoured dimple (1), which is deformable so as to compress the interior of the housing (EXAMPLES 7 and 9; figs. 9 and 13). The dimple also defines the interior of the housing (EXAMPLES 7 and 9; figs. 9 and 13). The dimple is located within the perimeter of the housing (fig. 13). The invention focuses on compressing the housing to generate a suction pressure to suck fluid into the capillary channel. Since the channels are of capillary dimensions, the capillary channel is capable of drawing fluid through the access port and into the capillary channel under capillary action. Furthermore, this particular embodiment discloses that the sample is introduced by capillary into a pooling portion (col. 23, lines 6-8). Analogous to the operation of a pipette, compressing the housing generates a suction force to draw fluid into the capillary channel and compressing the

housing now with fluid once again exerts an expelling force on the capillary channel to expel the fluid from the access port.

The dimensions of the drawing channels and the like in this fluid transfer device are disclosed as being the same as that in the device of EXAMPLE 7 as shown in fig. 9 (col. 22, lines 60-62). The capillary channel (2) is usually 0.5-2 mm in width (col. 20, lines 47-49). The access port is usually 2-10 mm in width. The channel (2) is considered a capillary channel since the channels have capillary dimension as evidenced by Levine et al., which discloses that channels of capillary dimensions--dimensions that favor capillary flow of a liquid--are no wider than about 1.5 mm (Levine et al.: col. 2, lines 45-50). Portions of the capillary channel is formed neared the perimeter of the first housing member (fig. 13). The capillary channel follows a tortuous path near the housing perimeter, as shown by the bends in the capillary channel (fig. 13). However, the path is not tortuous along the entire perimeter, as shown by the straight-line path along the perimeter having analytical section (3) (fig. 13). The access port is located adjacent the housing perimeter in communication with one end of the capillary channel (fig. 13). The other end of the capillary channel is in fluid communication with the interior of the housing (fig. 13). The capillary channel includes means for restricting fluid drawn therethrough by a fluid stop supported by the channel intermediate the housing interior and access port, such as a hydrophobic porous film (8) (figs. 9 and 13; col. 22, lines 47-50; col. 19, lines 25-27).

13. Claims 1, 3, 4, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,965,047 to Hammond as evidenced by U.S. Patent No. 5,958,344 to Levine et al.

Hammond discloses a fluid transfer device (figs. 1-5). A housing defines an interior and includes an access port (16) and elongate capillary channel in fluid communication with the

access port and housing interior for drawing fluid through the access port and into the capillary channel under capillary action (figs. 1-5). Alternatively, the access port may be defined by the opening through which the absorbent layer (42) projects beyond the housing or the tip of the exposed portion of the absorbent layer (col. 6, lines 49-51). The capillary channel may be considered the channel the absorbent layer resides or the plurality of capillary channels resident in the absorbent layer since liquids flow along the test strip through a wicking action, which is another term for capillary action as defined by Merriam-Webster Collegiate Dictionary's verb form of "wick" (figs. 1-5). Nevertheless, since the device is 80 mm long by 10 mm wide by 3 mm deep, the width of the absorbent layer is no larger than 10 mm, which is close to the typical capillary dimensions of 1.5 mm of Levine et al. The housing includes a first housing member or base member (42) and second housing member or covering (14) attachable to the first housing member by heat-sealing to define the housing interior (figs. 1-5; col. 3, lines 19-55). The second housing member includes an interiorly deformable contoured dimple (12), which is deformable so as to compress the interior of the housing (figs. 1-5). The dimple also defines the interior of the housing (figs. 1-5). The dimple is located within the perimeter of the housing (fig. 2). By compressing the dimple of the second housing member, an expelling force is exerted on the capillary channel to expel the liquid within the dimple along with the fluid from the access port (figs. 1-5; col. 3, line 56-col. 4, line 5). The dimple is non-resiliently deformable to provide evidence that the device has been used (col. 5, lines 45-64). The housing may include a plurality of interiorly deformable dimples defining the housing interior, and deforming the dimples causes the depression of the housing interior and expulsion of a predetermined-quantity of liquid within the dimple along with the fluid from the access port (col. 4, lines 6-21). The capillary channel is

formed neared the perimeter of the first housing member (figs. 1-5). The access port is located adjacent the housing perimeter in communication with one end of the capillary channel (figs. 1-5). The other end of the capillary channel is in fluid communication with the interior of the housing (figs. 1-5).

14. Claims 1, 3, 5-13, 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,916,522 to Boyd et al.

Boyd et al. disclose a fluid transfer device (figs. 1-9). A housing defines an interior and includes an access port (38,80) and a plurality of elongate capillary channels in fluid communication with the access ports and housing interior for drawing fluid through the access ports and into the capillary channels under capillary action (figs. 1-9). The housing includes a first housing member or base member (10) and second housing member or covering (18) attachable to the first housing member with a top plate (14) in between to define the housing interior (figs. 1-9; col. 4, lines 18-42). The first housing member includes a sidewall, which borders the capillary channel and extends from the lowest level at which the groove forming the channel dips and downwardly and laterally away from the channels to form a skirt with indentations (figs. 1-9). The sidewall mates with the second housing member skirt (28) (figs. 1-9). The housing includes a view window (23) in visual communication with the capillary channel (figs. 1-9; col. 5, lines 6-20).

The second housing member includes an interiorly deformable contoured dimple (20), which is deformable so as to compress the interior of the housing (figs. 1-9; col. 4, lines 43-58). The dimple also defines the interior of the housing (figs. 1-9). The dimple is located within the perimeter of the housing (figs. 1-9). The device includes a second interiorly deformable

contoured dimple (86) (figs. 1-9). Upon compression of the first dimple, which causes deformation of the housing, a pre-determined quantity of the sample fluid is expelled along the capillary channels into the electrochemical device (22) (figs. 1-9; col. 7, lines 29-44). Upon compression of the second dimple, which causes deformation of the housing, a predetermined quantity of the reference fluid is expelled along the capillary channels into the electrochemical device inlet (82) (figs. 1-9; col. 8, lines 13-38).

The channels are considered capillary channels since flow of liquids occurs by capillary action (col. 5, line 31-col. 6, line 8; col. 6, line 47-col. 7, line 28). Portions of the capillary channel is formed neared the perimeter of the first housing member (figs. 1-9). The capillary channel follows a tortuous path near the housing perimeter or at the end of the path before the vent passages (60,62), as shown by the bends in the capillary channel (figs. 1-9). However, the path is not tortuous along the entire perimeter, as shown by the straight-line path along the perimeter (figs. 1-9). The tortuous path may be considered a spiral configuration since it appears to wind around a center gradually receding or approaching it (figs. 1-9). Each access port is located adjacent the housing perimeter in communication with one end of the capillary channel (figs. 1-9). The other end of the capillary channel is in fluid communication with the interior of the housing (figs. 1-9). The capillary channel includes means for restricting fluid drawing therethrough, including channel configuration (col. 6, line47-col. 7, line 28). The spike in conjunction with a puncturable material, which is supported by the capillary channels intermediate the housing interior and the access port, is a fluid valve (col. 8, lines 13-38).

15. Claims 1, 2, 5, 8-12, 18, 20-23 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,343,717 to Zhang et al. as evidenced by U.S. Patent No. 5,958,344 to Levine et al.

Zhang et al. disclose a fluid transfer device (figs. 11-15 and 20-35). A housing defines an interior and includes an access port (88) and elongate capillary channel in fluid communication with the access port of the collection/dispensing tip (86) and housing interior for drawing fluid through the access port and into the capillary channel under capillary action (figs. 11-15 and 20-35). The housing is deformable so as to compress the housing interior and exert an expelling force on the capillary channel to expel fluid from the access port (figs. 11-15 and 20-35; col. 6, lines 4-26). The housing includes a bulb-shaped member (44) defining the interior of the housing (figs. 11-15 and 20-35). The housing includes a view window in visual communication with the capillary channel since the housing may be made of transparent or translucent materials (figs. 11-15; col. 4, lines 52-54).

Zhang et al. disclose that this embodiment is basically the same as the preferred embodiment except for the difference in structure as disclosed in this embodiment, such that the capillary channel within portion (46) typically would have an internal diameter of 0.5-2.5 mm (col. 6, lines 4-10; col. 5, lines 58 and 59). The channel is considered a capillary channel since the channels have capillary dimension as evidenced by Levine et al., which discloses that channels of capillary dimensions--dimensions that favor capillary flow of a liquid--are no wider than about 1.5 mm (Levine et al.: col. 2, lines 45-50). Furthermore, capillary action is even more favored since the access port near the tip is 2-3 times smaller than the internal diameter as that of the capillary channel within portion (46) (col. 6, lines 13-18). The capillary channel

extends from the bulb-shaped member to the access port (figs. 11-15 and 20-35). The capillary channel is formed about the perimeter of housing, and the housing is deformed within the perimeter (figs. 11-15 and 20-35). The capillary channel includes means for restricting fluid drawn therethrough, including channel configuration and fluid stop (58) supported by the channel intermediate the housing interior and access port (figs. 11-15 and 20-35). Figs. 20-35 show various male and female luer locks that may be removably attached on the access port (col. 5, line 60-col. 6, line 3). Fig. 31 shows a male-luer lock tip. Fig. 32 shows a female-luer lock tip. Fig. 20 shows a removably attached male-luer lock structure that fits into the access port. Figs. 21-23 show removably attached female-luer lock structure that fits over the access port. As described in this embodiment, any of these types of tips or covers may be used.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (571) 272-1261. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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eq

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